DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Central Expressway, #300 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	05/5-8 & 12-15/15
	FEI NUMBER 3011501377

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Tamara G. Mitchell, Co-Owner

FIRM NAME	STREET ADDRESS
Diamond Pharmacy, LLC	2900 Hillcroft St., Suite B
CITY, STATE AND ZIP CODE Houston, TX 77057	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:

The following observations pertain to the preparation of all drug products including Combination Cream, Joint Compound Cream, Anti-Inflammatory Cream, Musculoskeletal Compound Cream, Neuro Pain Compound Cream, Eczema Cream and Anti-Fungal Cream.

OBSERVATION 1:

Batch production and control records are not prepared for each batch of drug product produced and do not include complete information relating to the production and control of each batch.

Specifically,

a) Formula Worksheets (batch records) for each drug product prepared by your firm are deficient. Deficiencies include the following.

i. Formula Worksheets are not created and prepared at the time that a drug product is made. All drug products are prepared first and then a Formula Worksheet is created for each order. On 5/5/15, there were several products on the counter in the area where drug products are prepared that had been made and packaged but for which there is no Formula Worksheet. These include (b) (4) gram bottles of Combination Cream and (b) (4) gram bottles of Eczema Cream.

ii. Your Formula Worksheets do not reflect the actual process of preparing each drug product. For example, for the preparation of the Combination Cream product, a separate Formula Worksheet with a unique lot number is generated for each individual order. A typical batch size is (b) (4). Your practice is to weigh out and (b) (4) raw materials/ingredients for each individual order along with the (b) (4). You then

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(b) (4) for each individual order. All raw materials for (b) (4) and (b) (4) This (b) (4) Your Formula Worksheets don't reflect the (b) (4); (b) (4) are (b) (4) (b) (4) and if there are different lot numbers of raw materials (active pharmaceutical ingredients and excipients) used that may be (b) (4) are (b) (4)

iii. Your Pharmacist-In-Charge (PIC) stated that each batch made for an order is prepared using the batch size in the sheets she refers to while preparing the product and not from the actual Formula Worksheet for that specific lot. For example, a standard batch size for the Combination Cream and Musculoskeletal Compound Cream is (b) (4) Formula Worksheets have been created for (b) (4) batches, however, the actual amount prepared was (b) (4) Examples include lot #s:

- 01-08-2015@13 ((b) (4) of Combination Cream),
- 01-09-2015@9 (b) (4) of Combination Cream),
- 02-10-2015@12 ((b) (4) of Musculoskeletal Compound Cream),
- 02-10-2015@25 (b) (4) of Combination Cream),
- 03-18-2015@6 ((b) (4) of Combination Cream),
- 03-18-2015@13 ((b) (4) of Musculoskeletal Compound Cream),
- 03-18-2015@2 ((b) (4) of Combination Cream) and
- 03-18-2015@12 ((b) (4) of Musculoskeletal Compound Cream).

iv. There is no verification made of the actual lot numbers of each active pharmaceutical ingredient (API) and excipient used in the preparation of a batch. For example, in the Formula Worksheet for lot #12-29-2014@28 of Combination Cream, the lot number for the Ketamine HCl USP used is listed as (b) (4) This is not a correct lot number for this API. This is a lot number for (b) (4) In the Formula Worksheet for lot #12-16-2014@23 of Combination Cream, the lot number for the Ketamine HCl USP used is listed as (b) (4) This is an incorrect lot number for this API. This is a lot number for Cyclobenzaprine HCl USP.

v. Your firm does not identify in the Formula Worksheet the actual scale/balance and (b) (4) used in the preparation of drug products. Your firm has (b) (4) but serial number unable to be determined) and (b) (4) (no serial numbers) scales and (b) (4) that can be used.

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b) There were (b) (4) containers of Neuro Pain Compound Cream, (b) (4) containers of Anti-Inflammatory Cream, (b) (4) container of Alt. Joint Cream, (b) (4) containers of Musculoskeletal Compound Cream, and (b) (4) gram containers of Combination Cream in totes on the shelf above the area where drug products are prepared. The containers did not have any lot numbers to identify when they were made and were labeled as samples. Your firm did not have any Formula Worksheets to show when these drug products were prepared. Your firm has documentation of at least two shipments of samples on 8/27/14 and 9/29/14 to (b) (4) Your Pharmacy Technician/Office Manager also stated that these containers labeled as samples are being distributed.

OBSERVATION #2:

Records fail to include an individual inventory record of each component and the reconciliation of the use of each component with sufficient information to allow determination of any associated batch or lot of drug product.

Specifically,

a) Your firm does not maintain accurate inventory records of each lot of each active pharmaceutical ingredient (API) and excipient received and used to make drug products. For example,

i. Your firm has documentation to show that (b) (4) of lot # (b) (4) of Ketamine HCl USP was received from your supplier in 3 shipments received on (b) (4) Information from the (b) (4) software program shows that this lot was used to make (b) (4) lots of Musculoskeletal Compound Cream, (b) (4) lots of Combination Cream, (b) (4) lots of Joint Compound Cream, and (b) (4) lots of Neuro Pain Compound Cream. The total amount of Ketamine HCl USP that would be used for these (b) (4) lots is (b) (4) Your firm has none of this lot in inventory and cannot account for the use of the additional (b) (4) from this lot.

ii. Your firm has documentation to show that (b) (4) of lot # (b) (4) of Ketamine HCl USP was received from your supplier on 11/26/14. Information from the (b) (4) software program shows that this lot was used to make

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(b)(4) lots of Musculoskeletal Compound Cream, (b)(4) lots of Combination Cream, (b)(4) lots of Joint Compound Cream, and (b)(4) lots of Neuro Pain Compound Cream. The total amount of Ketamine HCl USP that would be used for these (b)(4) lots is [redacted] (b) (4).

iii. Your firm has documentation to show that [redacted] (b) (4) of lot (b) (4) [redacted] of Ketamine HCl USP was received from your supplier on 12/29/14. There is none of this lot in inventory and your firm has no documentation showing the use of this lot of Ketamine HCl USP.

b) Your firm has documentation showing that [redacted] (b) (4) of all lots of Ketamine HCl USP were received by your firm from February 2014 to April 2015. Information from the (b)(4) software program regarding all lots and amounts of Ketamine HCl USP used in all drug products made from 3/6/14 through 5/5/15 shows that [redacted] (b) (4) of Ketamine HCl USP were used. Subtracting what is currently in inventory ((b) (4) [redacted]), your firm cannot account for approximately [redacted] (b) (4) of Ketamine HCl USP.

OBSERVATION #3:

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

Specifically, your firm has no in-process control procedures to ensure that each drug product made by your firm is adequately mixed. You do not test in-process blend samples for adequacy of mixing to ensure uniformity and homogeneity of all lots of drug products prepared.

OBSERVATION #4:

Batch production and control records do not include the identification of the persons performing and checking each significant step in the operation, for each batch of drug product produced.

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Specifically, your firm does not have a unique username and password for each person who logs in and enters information into the (b) (4) Software system regarding the preparation of a batch/lot of drug product. Your Pharmacist-in-Charge (PIC) stated that she does not enter information into the computer system however, all entries in the Formula Worksheets for each batch prepared are identified as having been performed by the PIC. A Pharmacy Technician creates the Formula Worksheet for each batch of drug product after it is prepared.

OBSERVATION #5:

Actual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of processing, packaging and holding of the drug product.

Specifically,

For example,

a) Lot #08-08-2014@1 of Combination Cream was made on 8/8/14. The Formula Worksheet indicates that (b) (4) were made but your records show only (b) (4) were distributed. There is no documentation of how the other (b) (4) were packaged or the disposition of this product.

b) Lot #09-10-2014@1 of Combination Cream was made on 9/10/14. The Formula Worksheet indicates that (b) (4) were made but your records show only (b) (4) were distributed. There is no documentation of how the other (b) (4) were packaged or the disposition of this product.

c) Lot #09-30-2014@16 of Combination Cream was made on 9/30/14. The Formula Worksheet indicates that (b) (4) were made but your records show only (b) (4) were distributed. There is no documentation of how the other (b) (4) was packaged or the disposition of this product.

d) Lot #01-06-2015@57 of Combination Cream was made on 1/6/15. The Formula Worksheet shows that (b) (4) were made but your records show only (b) (4) were distributed. There is no documentation of how the other (b) (4) were packaged or the disposition of this product.

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e) Your PIC stated that periodically she may have to discard drug product that is not (b) (4) [redacted] She said that this primarily can happen with the Combination Cream. There is no documentation of this happening or of the amount of product that is discarded. Your PIC stated that she may have discarded product 1-2 times in April 2015.

OBSERVATION #6:

Batch production and control records do not include the weights and measures of components used in the course of processing each batch of drug product produced.

Specifically, Formula Worksheets for each lot of drug product made are created by your firm after the drug product has already been prepared. The actual weight of each component used is not documented.

OBSERVATION #7:

Distribution records do not contain the name and strength of the drug product, description of dosage form, date and quantity shipped, and lot or control number of drug product.

Specifically,

a) Your firm has documentation of at least two shipments on 8/27/14 and 9/29/14 to (b) (4) [redacted] of samples. Your firm has no documentation to show what products or lot numbers were included in these shipments or the quantity of product sent.

b) Your firm has documentation of the shipment of [redacted] of Combination Cream (Rx (b) (4), (b) (6)) on 12/9/14 to a customer in [redacted] Your firm has no documentation of the lot number that was shipped and no copy of the Formula Worksheet showing the preparation of the lot sent.

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OBSERVATION #8:

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, drug products made and distributed by your firm do not have an expiration date or beyond-use-date (BUD) on product label.

OBSERVATION #9:

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

Specifically, your firm does not have a written stability testing program to determine Beyond Use Dates (BUD) to be placed on your drug products. Your firm is not placing a BUD on your drug products, however, the Formula Worksheets prepared for each drug product indicate that the BUD is 30 days from the date of preparation.

OBSERVATION #10:

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

Specifically, your firm has no documentation to show that the (b) (4) [redacted] serial number unable to be determined) and (b) (4) [redacted] (no serial numbers) scales used to weigh raw materials, including APIs, have been calibrated.

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OBSERVATION #11:

Procedures describing the handling of all written and oral complaints regarding a drug product are not established.

Specifically, your firm has no written procedure for the documentation and handling of complaints that are received. Your firm has documentation received in January 2015 from the Chief Medical Examiner's office in Harris County requesting information about all ingredients and concentrations for the Combination Cream and any additional prescriptions filled at the pharmacy as part of an investigation into the death of a patient who was shipped medication by your firm. There is no documentation of an investigation being performed or documentation of a review to determine if this was a serious or unexpected adverse drug experience that needed to be reported to FDA.

OBSERVATION #12:

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, your firm has no written procedures for the cleaning of equipment used to make drug products including scoops, spatulas and bowls. Your PIC stated that equipment is (b) (4) [redacted]. Your firm has not validated this cleaning method to ensure that equipment is clean and that there is no cross contamination or carryover of drug product from one batch to the next.

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