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	12/11/2018-12/19/2018* FEI NUMBER 3010710511

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jerrod L. Roberts, DPh, President/Owner

FIRM NAME	STREET ADDRESS
Flourish Integrative Pharmacy, LLC	14720 N Pennsylvania Ave
CITY, STATE, ZIP CODE, COUNTRY Oklahoma City, OK 73134-6120	TYPE ESTABLISHMENT INSPECTED 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

Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically, your firm uses (b) (4) water in certain drug products whose formulation requires water. Your firm is also using the (b) (4) water to (b) (4) Water ((b) (4)) and (b) (4) Water ((b) (4)) for use in certain drug products. Your firm does not perform testing (analytical or microbiological) to show the water at least/at minimum meets the specifications for Purified Water, USP.

Examples of products made using the (b) (4) water include:

- lot #BDIHIG:73 of Tetracaine HCl Nasal 2.5% Solution prepared on 11/12/18
- lot #BDIJHH:11 of Chloral Hydrate 100 mg/mL Syrup prepared on 11/15/18
- lot #BDJDEH:64 of (b) (4) prepared on 11/27/18

Examples of lots made using the (b) (4) Water made from the (b) (4) water include:

- lot #BDFIEEE:17 of Ketamine Spray 20% Nasal prepared on 8/24/18 using (b) (4) Water ((b) (4))
- lot #BDEEDI:67 of Diclofenac/Hyaluronic Acid 3/1.74% Gel prepared on 7/19/18 using (b) (4) Water ((b) (4))

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Margaret M Annes, CSO	DATE ISSUED 12/19/2018

X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 12-19-2018 09:00:27

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Oklahoma City, OK 73134-6120	Producer of Non-Sterile Drugs

OBSERVATION 2

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) placed on all your drug products. For example,

a. Your firm has no documentation to justify the BUD placed on lot #BDJDEH:64 prepared on 11/27/18 and lot #BDIIDF:41 prepared on 11/12/18 of (b) (4) . The BUD assigned was 180 days after preparation.
b. Lot #BDIJHH:11 of Chloral Hydrate 100 mg/mL Syrup prepared on 11/15/18 contains (b) (4) water. The BUD assigned is 90 days after preparation at room temperature.

OBSERVATION 3

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 routine testing for potency for all drug products produced by your firm.

***DATES OF INSPECTION**

12/11/2018(Tue), 12/12/2018(Wed), 12/13/2018(Thu), 12/19/2018(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Margaret M Annes, CSO X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 12-19-2018 09:00:27	12/19/2018