DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

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 ORAPharm2_responses@fda.hhs.gov	11/18/2019-11/22/2019* FEI NUMBER 3004102002

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jack R. Munn, Owner/Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
MPRX, Inc. dba Medical Park Pharmacy	8230 Elmbrook Dr Ste 600B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dallas, TX 75247-4144	Producer of Non-Sterile Drugs

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically, during my review of your October 2019 Formula Worksheets, (b) (4) of (b) (4) lots of products were produced using at least one expired bulk drug substance/chemical including, but not limited to the following: Phenylephrine, Desonide, Dexamethasone, Liothryonine, Acesulfame Potassium, Gabapentin and Cyclobenzaptine.

OBSERVATION 2

Calibration of mechanical equipment is not performed daily or an a routine schedule designed to assure proper performance.

Specifically,

a) You have not calibrated the scale used to weigh bulk drug substances/chemicals since you moved to this location.
b) You stated, and I observed you do not verify the weighing of ingredients/components for each lot made.
c) Formula Worksheets do not list ingredients and the quantity of each in the order of the manufacturing process.

OBSERVATION 3

You produced highly potent drugs without providing adequate to prevent cross-contamination.

Specifically, you do not document the cleaning of the (b) (4) hood and the hood used and non-dedicated equipment (i.e. (b) (4) , etc.) to demonstrate control of cross contamination between highly potent drugs.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Claire M. Minden Digitally signed by Claire M. Minden -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300178102, cn=Claire M. Minden -S Date: 2019.11.22 13:34:56 -06'00'	Claire M. Minden, Investigator	11/22/2019

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314 ORAPharm2_responses@fda.hhs.gov	11/18/2019-11/22/2019*
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OBSERVATION 4

Vermin was observed in your production area.

Specifically, on November 20, 2019, I observed an insect in the pharmacy area on the floor where compounding activities occur.

***DATES OF INSPECTION**

11/18/2019(Mon), 11/19/2019(Tue), 11/20/2019(Wed), 11/22/2019(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
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