OBSERVATION #1

On 6/25/18, during the aseptic processing of Dexamethasone NAPO4 24mg/ml Injectable, lot #06252018@1, an operator was observed placing her gloved hands outside the ISO 5 area and not re-sanitizing prior to placing her gloved hands under the ISO 5 hood. The same operator was observed wearing a face mask and hairnet which left the skin of her forehead partially exposed. The operator was observed to introduce the exposed skin of her forehead inside the ISO 5 hood.

OBSERVATION #2

Your firm does not test all lots of intrathecal drug products for endotoxin prior to release.

In addition, the stock solution for Baclofen (Baclofen USP Powder and Sodium Chloride) is (b) (4) and never tested for sterility or endotoxin after initial and repeated use.

Your firm produced 6(4) lots of intrathecal drug products between 3/25/18-6/26/18 which were not tested for endotoxin prior to being dispensed to patients. For example, Baclofen Intrathecal 1000mcg/ml Injectable, lot #05072018@71 was produced on 5/7/18 under Rx i(b) (6) for patient (b) (6)

OBSERVATION #3

On 6/27/18, I observed that the magnahelic gauge monitoring differential pressure between the ISO 8 anteroom and unclassified area was at “0”. In addition, the gauge used to monitor the pressure between the ISO 7 cleanroom and ISO 8 anteroom was not working. During this time, an operator was preparing the following two lots of intrathecal drug product under the ISO 5 hood which were dispensed to patients:

AMENDMENT-1
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DATE(S) OF INSPECTION
6/25/18-7/2/18

FEI NUMBER
3003780900

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Christopher S. Gilbert, Pharm.D., Owner/Pharmacist in Charge

FIRM NAME
People's Custom Rx and Clinical Care, LLC

STREET ADDRESS
785 Brookhaven Circle East

CITY, STATE AND ZIP CODE
Memphis, TN 38117-4501

TYPE OF ESTABLISHMENT INSPECTED
Producer of Sterile and Non-Sterile Drug Products

A. Morphine/Baclofen Intrathecal 35mg-100mcg/ml Injectable, lot #06272018@14 (Rx #(b) (6) for patient (b) (6)

B. Morphine/Bupivacaine Intrathecal 40mg-20mg/ml Injectable, lot #06272018@3 (Rx #(b) (6) for patient (b) (6)

OBSERVATION #4

SOP # 3.300.303 entitled, "Disinfectant Solution and (b) (4) " (Effective date: 9/1/17) does not identify the contact time used for the (b) (4) and (b) (4) disinfectants. In addition, there is no documentation to substantiate the (b) (4) minute contact time currently in use.

OBSERVATION #5

Your firm uses a (b) (4) for the depyrogenation of glassware used in the production of sterile, injectable drug products. The (b) (4) used for depyrogenation for (b) (4) minutes has never been verified.

In addition, the (b) (4) is located in an area which is not in close proximity to the ISO 5 hood. In this case, the (b) (4) is located in the ISO 8 anteroom which requires that depyrogenated glassware be transferred through a door leading into the ISO 7 cleanroom for subsequent storage.

AMENDMENT-1

Employee(s) Signature

Employee(s) Name and Title (Print or Type)
Stephen D. Brown, Investigator

Date Issued
07/19/2018