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,

Your firm produced finished Testosterone Cypionate 200MG/ML in Grapeseed Oil lots AL-07192018@906 and AL-08072018@901 using apparent food-grade Grapeseed oil supplied by (b)(4) and labeled by the manufacturer as “Caution: Dietary Supplement.” According to your firm’s batch record,

- Your firm produced (b)(4) finished vials of lot AL-07192018@906 using Grapeseed Oil, lot 1801260072. For example, the shipping record shows that a vial of lot AL-07192018@906 was delivered to RX (b)(6) in (b)(6) on 08/22/18.
- Your firm produced (b)(4) finished vials of lot AL-08072018@901 using Grapeseed Oil, lot 1801260072. For example, the shipping record shows that a vial of lot AL-08072018@901 was delivered to RX (b)(6) in (b)(6) on 08/29/18.

Observation 2
Visual inspection of finished drug products prior to distribution is not adequately performed. Specifically,

Your firm (b)(4) sterilized Testosterone Cypionate 200 MG/ML in Grapeseed Oil injectable lots AL-07192018@906 and AL-08072018@901 at (b)(4) °C for (b)(4) minutes, respectively on 07/24/18 and 08/07/18. Your firm stated that 100% visual checks are performed on each lot prior to labeling and dispensing or distribution to your patient. However, your firm does not utilize any black or white box or additional lighting source to examine for visible particulates, cloudiness, and/or discoloration in the finished vials.

For example:
- Your firm produced (b)(4) finished vials from lot AL-07192018@906. Your firm shipped a vial from this lot to RX (b)(6) in (b)(6) on 08/22/18.
- Your firm produced (b)(4) finished vials from lot AL-08072018@901. Your firm shipped a vial from this lot to RX (b)(6) in (b)(6) on 08/29/18.

OBSERVATION 3

Non-sterile, low-shedding wipes are used to cleaned the ISO 5 hoods. Specifically,
On 08/27/18, I observed non-sterile wipes ((b) (4), (b) (4)) in the ISO 7 clean room. Your firm stated that these non-sterile wipes utilized during the routine cleaning of the ISO 5 hoods.

*DATES OF INSPECTION
8/27/2018(Mon), 8/28/2018(Tue), 8/29/2018(Wed), 8/30/2018(Thu), 8/31/2018(Fri), 9/04/2018(Tue), 9/05/2018(Wed), 9/07/2018(Fri)