During an inspection of your firm I observed:

Observation 1

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Your firm produces products intended for intrathecal use from non-sterile active ingredients that are not controlled for endotoxin level. In addition, your firm does not test final product to ensure the product is within allowable limits for bacterial endotoxins.

Observation 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically, your smoke studies for ISO 5 hood, serial number (b) (4) , test report (b) (4) and for ISO 5 hood, serial number (b) (4) , test report (b) (4) , performed on (b) (4) , are inadequate in that they failed to demonstrate unidirectional airflow studies (smoke studies) under dynamic conditions to determine how the movement of air and personnel during aseptic operations could pose risk to products.

Observation 3
Procedures for the cleaning and maintenance of equipment are deficient regarding inspection of the equipment for cleanliness immediately before use.

Specifically, Your firm uses non-sterile wipes in your sterile compounding area. For example, non-sterile wipes are used when cleaning the ISO 5 hood, cleaning of equipment in both the ISO 7 and ISO 8 areas, and by employees during hand washing activities in the ISO 8 area.

*DATES OF INSPECTION*
1/17/2017(Tue), 1/18/2017(Wed), 1/19/2017(Thu), 1/20/2017(Fri), 1/25/2017(Wed), 1/26/2017(Thu), 1/31/2017(Tue), 2/02/2017(Thu), 2/03/2017(Fri), 2/09/2017(Thu), 3/14/2017(Tue)