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 does not have assurance that your intrathecal drug products contain safe levels of bacterial endotoxin (BET). The non-sterile active pharmaceutical ingredients (API) bupivacaine, hydromorphone, and morphine sulfate used in the production of those intrathecal drugs do not contain results for BET testing on their Certificates of Analysis (CoA). Due to this, and combined with the fact that you do not perform testing on your intrathecal drug products – the result is a lack of assurance that your intrathecal products produced with those API are free from BET.

OBSERVATION 2

Disinfecting agents and cleaning pads or wipes used in the ISO 5 area are not sterile.

Specifically,

Your firm uses (b) (4) and (b) (4) in your ISO 5 area. Neither of these products is considered self-sterilizing and you do not use sterile versions, or perform sterilization actions on these cleaners. This could result in contamination of your sterile production area by microorganisms and thus risk contamination of your product.