OBSERVATION 1

The final containers/closures used for drug product intended to be sterile were not sterilized.

Specifically,

Finished product containers, closures, product contact beakers, and mixing rods which are treated for sterilization are wrapped in aluminum foil and stored in an ISO 7 room without an established hold time to ensure that these items remain sterile.

This observation is a repeated objectionable condition reported during the last inspection.

OBSERVATION 2

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

a. The firm fails to use (b)(4) during the compounding of non-sterile drug products. For example, Potassium Bromide (VET) Oral 300 mg/mL solution, Buprenorphine 0.3 mg/mL liquid, and Dexamethasone 0.5 mg/mL oral rinse.

b. The firm has not conducted microbiological testing of the (b)(4) used in non-sterile production. This (b)(4) has been used as a component during the production of Potassium Bromide (VET) Oral 300 mg/mL solution, Buprenorphine 0.3 mg/mL liquid, and Dexamethasone 0.5 mg/mL oral rinse.