DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Environmental monitoring was not performed in your aseptic processing areas.

Specifically, (b) (4) samples collected within the ISO 8 (b) (4) and (b) (4) areas, ISO 7 (b) (4) room, and (b) (4) ISO 5 laminar flow hoods, are only collected on a (b) (4) basis after cleaning.

OBSERVATION 2

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

Specifically, Your firm uses a non-sterile, non-sporecidal disinfectant (b) (4) with non-sterile wipes for all surfaces within the ISO classified areas, including in the ISO 5 laminar flow hoods where aseptic processes are conducted.

OBSERVATION 3

There is insufficient data to support the percentage of preservative used to ensure anti-microbial effectiveness in multi-dose stock solutions which are used to formulate finished product.