Sterile, injectable liquid dosage form preparation

OBSERVATIONS

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

Specifically,

Records to demonstrate the cleanroom meets the required grade suitable for sterile filling are inadequate.

For example.

a. Air changes reported by the contracted provider of service do not meet ISO 5 and ISO 6 standards.

b. Although the suite designated for sterile processing uses magnehelic gauges, there are no records to demonstrate the differential pressure conditions suitable for ISO 5, ISO 6 and ISO 7 are maintained during sterile filling.

c. Environmental monitoring records do not include continual sampling of non-viable particles to show the rooms/hoods classified as ISO 5, ISO 6 or ISO 7 maintain acceptable conditions for intended operations.