

TABLE 2. Recommended Action Levels for Microbial Contamination*
 †(cfu per cubic meter [1000 liters] of air per plate)

| CLASSIFICATION | AIR SAMPLE† |
|----------------------|-------------|
| ISO Class 5 | > 1 |
| ISO Class 7 | > 10 |
| ISO Class 8 or worse | > 100 |

*Guidance for Industry—Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice—US HHS, FDA September 2004.

TABLE 3. Minimum Frequency of Cleaning and Disinfecting Compounding Areas

| SITE | MINIMUM FREQUENCY |
|--------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO Class 5* Primary Engineering Control (e.g., LAFW, BSC, CAI, CACI) | At the beginning of each shift, before each batch, not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring, after spills, and when surface contamination is known or suspected |
| Counters and easily cleanable work surfaces | Daily |
| Floors | Daily |
| Walls | Monthly |
| Ceilings | Monthly |
| Storage shelving | Monthly |

*ISO Class 5 also called Class 100 allows a particle count of 3,520 per m³ or 100 particles per cubic foot.

TABLE 4. Recommended Action Levels for Microbial Contamination*

| CLASSIFICATION | FINGERTIP SAMPLE | SURFACE SAMPLE (CONTACT PLATE) (CFU PER PLATE) |
|----------------------|------------------|---------------------------------------------------|
| ISO Class 5 | > 3 | > 3 |
| ISO Class 7 | N/A | > 5 |
| ISO Class 8 or worse | N/A | > 100 |

*Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products Annexes PE 009-6, 5 April 2007.

Tables are adapted from USP 38-NF 33 Chapter <797> Pharmaceutical Compounding—Sterile.