

Manual 056

6. Appendices

Appendix A. Comparison table particles ISO 14644-1, EU GMP Annex 1 and FDA.

| EN ISO 14644-1 | | | | | | EU GMP Annex 1 | | | | FDA | | |
|--|---------|-----------|--|--------|-----------|----------------|---|--------------|---|--------------|-----------------------|---|
| At rest | | | In operation | | | Grade | At rest | | In operation | | Description | In operation |
| Maximum permitted number of particles/m ³ equal to or above | | | Maximum permitted number of particles/m ³ equal to or above | | | | Maximum permitted number of particles/m ³ (ft ³) equal to or above | | Maximum permitted number of particles/m ³ (ft ³) equal to or above | | | Maximum permitted number of particles/ft ³ (m ³) equal to or above |
| 0,5 µm | 5 µm | ISO Class | 0,5 µm | 5 µm | ISO Class | 0,5 µm | 5 µm | 0,5 µm | 5 µm | | 0,5 µm | |
| 3,520 | 29 | 5 | 3,520 | 29 | 5 | A | 3,500 (100) | 1 | 3,500 (100) | 1 | Critical | 100 (3,520) |
| 3,520 | 29 | 5 | 352,000 | 2,930 | 7 | B | 3,500 (100) | 1 | 350,000 (10,000) | 2,000 (57) | Supporting Clean Area | 10.000 (352,000) |
| 352,000 | 2,930 | 7 | 3,520,000 | 29,300 | 8 | C | 350.000 (10.000) | 2.000 (57) | 3,500,000 (100,000) | 20,000 (570) | Controlled | 100.000 (3,520,000) |
| 3,520,000 | 29,300 | 8 | - | - | - | D | 3,500,000 (100,000) | 20,000 (570) | - | - | - | - |
| 35,200,000 | 293,000 | 9 | - | - | - | - | - | - | - | - | - | - |

* - = not defined

Note: Additional reference for monitoring is USP Chapter 1116.

Appendix B. Comparison table microorganisms EU GMP Annex 1 and FDA.

| EU GMP Annex 1 | | | | | FDA | | |
|----------------|---|--|--|---------------------------------------|-----------------------------------|--|---|
| Grade | Recommended limits for microbial contamination in operation (a) | | | | Description (In Operation) | In operation | |
| | Air sample cfu/m ³ | Settle plates (diam. 90 mm) cfu/4 hours (b) | Contact plates (diam. 55 mm) cfu/plate | Glove print 5 fingers cfu/glove | | Microbiological Active Air Action Levels | Settle plates (diam. 90 mm) cfu/4 hours |
| A | <1 | <1 | <1 | <1 | Critical area (100) | <1 | <1 |
| B | 10 | 5 | 5 | 5 | Supporting Clean Area (10000) | 10 | 5 |
| C | 100 | 50 | 25 | - | Supporting Clean Area (100000) | 100 | 50 |
| D | 200 | 100 | 50 | - | Supporting Clean Area (undefined) | - | - |

(a) These are average values.

(b) Individual settle plates may be exposed for less than 4 hours.

* - = not defined