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Editorial Open Access

Attainment of Sterility and Satisfactory Material Functional Compatibility to Devices in the Clean Room

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A high-level aseptic environment must be maintained in bio-cleanrooms used for the manufacture of sterile products. Formaldehyde gas exposure was conventionally used to sterilize within bio-cleanrooms (ISO 14644-1), but Ministry of Health, Labor and Welfare Japan requires quite strict residual limitation of formaldehyde at less than 0.08 ppm because formaldehyde causes one of sick-house disease, so there was a need to seek for a less toxic alternative sterilants. These sterilants are ozone, hydrogen peroxide, peracetic acid and chlorine dioxide gases.

The authors have developed revolutionary new sterilization system using high concentration ozone gas and used this system to sterilize an actual bio-cleanroom. This system integrates the ozone gas generator with the air conditioning system by proper control. The design specification for the system was the achievement of an ozone gas concentration of 200 ppm or more, relative humidity of 80% or more and sterilizing time of 120 mins. Blow vents and suction ports were placed to ensure a uniform airflow which would extend through the entire room during ozone gas sterilization.

Long-term exposure for material and functional compatibility tests to ozone gas exposure were conducted when the system was introduced to distinguish the usable members from the unusable members. In an actually constructed cleanroom, simulations were used to predict the evenness of the diffusion of ozone gas concentration and relative humidity during ozone gas sterilization, and measurements of the actual indoor ozone gas concentration, temperature and relative humidity during sterilization revealed that the ozone concentration and relative humidity needed for sterilization had been achieved generally throughout the entire environment. In addition, the CT value (mg/m^3 (=ppm) X min), derived by multiplying the ozone gas concentration during ozone gas sterilization by the sterilization time, was equal to or more than the target value of $24X10^3$ (ppm*min). When the results of sterilization in a cleanroom were confirmed using a biological indicator (BI), negative results were obtained at all measurement points including cold points, demonstrating that sterilization is being performed effectively in the actual factory at which the ozone gas sterilization system has been introduced.

These results indicate that the current procedure is appropriate to attain both sterility assurance (SAL) of 10^{-6} and material and functional compatibility.

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