

無菌医薬品包装の欠陥を通過できる微粒子の大きさ

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Can Particulate Matter in the Manufacturing Environment Pass Through Packaging Defects in Sterile Products?

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Summary

We investigated whether or not particulate matter (PM) in the manufacturing environment can penetrate into sterile products through packaging defects via the air. The sedimentation velocity of PM, the moving distance of individual particles due to Brownian motion, and the van der Waals force between particles and the surface of a packaging defect were calculated by using well-known theoretical equations of physical chemistry.

We calculated that particles having a diameter of 0.2 to 20 μm that penetrate into a packaging defect having a pore size of about 50 μm collide with the surface of the packaging defect within a few seconds at the longest. In addition, particles of about 0.2 to 20 μm that are adsorbed on a packaging defect cannot easily leave the surface of the defect due to the van der Waals force between the particle and the surface.

In conclusion, the risk of airborne PM, including microorganisms, invading sterile products through packaging defect in the GMP manufacturing environments appears to be limited.

Key words

Packaging defects, Particulate matter, Sedimentation velocity, Moving distance by Brownian motion, Van der Waals force, Manufacturing environment, Airborne particles, Airborne microorganism