Bacterial Endotoxin Testing

Bacterial endotoxin is a complex of lipopolysaccharide (LPS) and protein in the cell wall of gram-negative bacteria, which is released when the bacteria die or autolysis. A large amount of endotoxin enters the bloodstream and causes a febrile reaction - a "pyrogenic reaction". If endotoxin enters and collects in the blood in large quantities and exceeds the clearance capacity of the body's self-defense system, endotoxemia of different degrees may result. Therefore, biological products, pharmaceuticals for injection, chemicals, radiopharmaceuticals, antibiotics, vaccines, dialysis solutions and other preparations, as well as medical devices (such as disposable syringes and implantable biological materials) must be tested for bacterial endotoxin before use.

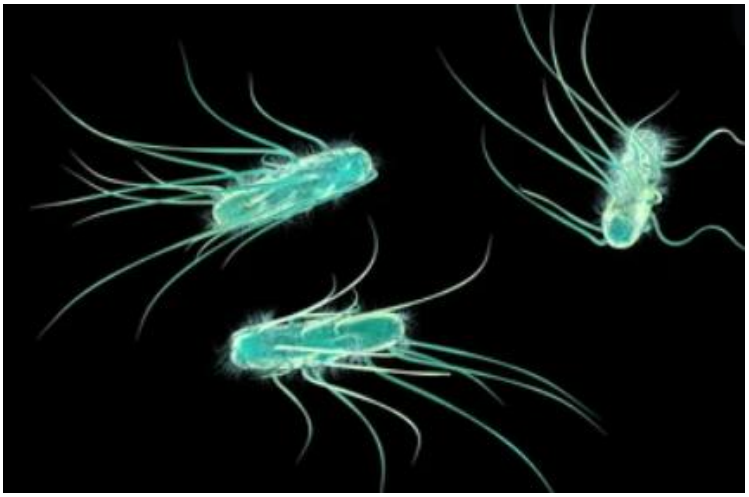

Fig.1 3D image of bacterial endotoxin

Different samples need to find the corresponding interfering factors, find the type of interfering effect, find the method to eliminate the interference, go through method validation, determine the method, and then perform daily testing.

Frequently Asked Questions

How to pretreat the insoluble water donor?

The corresponding solvent can be selected according to the characteristics of the test itself, such as dimethyl sulfoxide, ethanol, etc. Corresponding solvents, need to be verified without interference effect and its own endotoxin content.

How many times does the method applicability study need to be conducted?

When establishing endotoxin screening methods for injectable drugs and biological products, it is necessary to use two multiple reagent manufacturers at the same time, and at least three batches of samples of each species for interference testing.

Source: https://www.formulationbio.com/bacterial-endotoxin-testing.html